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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,783	04/18/2005	Andreas Axen	PU02103	1857
22840 7590 02/24/2009 GE HEALTHCARE BIO-SCIENCES CORP. PATENT DEPARTMENT 800 CENTENNIAL AVENUE PISCATAWAY, NJ 08855				
EXAMINER VALENROD, YEVGENY				
ART UNIT		PAPER NUMBER		
1621				
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02/24/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,783

Applicant(s)

AXEN ET AL.

Examiner

YEVEGENY VALENROD

Art Unit

1621

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-19, 21-23 and 26-34 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-19, 22, 23, 26, 28-30, 33 and 34 is/are rejected.
- 7) ☒ Claim(s) 27, 31 and 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Rejection of claims 17-19 and 22-34 under 35 USC 112nd paragraph is withdrawn in view of applicants' amendment to the claims.

Rejection of claims 17-19, 22-25, 28-30 and 33-34 under 35 USC 1st paragraph for lacking written description is withdrawn in view of applicants' amendment to the claims.

Rejection of claims 17-19 and 22-24 under 35 USC 1st paragraph for lacking written description is withdrawn in view of applicants' amendment to the claims.

Amendment to the claims filed 8/27/07 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what the term terminating functionality means. Since R4 is the moiety linking the urea derivative of the instant invention with the matrix, it is unclear how it can comprise a terminating functionality. If the functionality is in fact terminal, then is there no support attached to the urea derivative?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-19, 22, 23, 26, 28, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuyama et al (EP 0743067)

Instant claims are directed to a separation matrix comprising affinity ligand of formula (I). Limitations in some of the dependent claims comprise a property of the ligand wherein the ligand is capable of binding to the constant region of a Fab fragment of human IgG.

Scope of prior art

Fukuyama et al teach support linked aryl urea (chitosan beads with structural formula 2, page 6, lines 1-10) derivatives in adsorption of antigens.

Ascertaining the difference

Fukuyama et al fail to teach that their urea compound posses affinity for the instantly claimed Fab fragment.

The compounds of Fukuyama et al differs from the instantly claimed compound in that R1 in Fukuyama et al is a H not methyl or ethyl groups as required by the instant claim 1.

Obviousness

Hydrogen - Methyl substitution is obvious.

One skilled in the arts would find it obvious to substitute the N-Hydrogen of Fukuyama for N-Methyl group as in the instant claims. Compounds of Fukuyama are biologically active compounds and substitution is not considered to significantly alter the biological properties of the compound because the compounds would be of the same homologous series. Members of homologous series must possess unexpected properties not possessed by the homologous compounds disclosed in the prior art. In re Hass 141 F.2d 127, 60 USPQ 548 (CCPA 1944). The matrix of the instant invention is therefore obvious.

Binding affinity for the Fab fragment

The binding affinity of the instantly claimed compound is an inherent property the claimed compound. This inherent property is also present in the compounds that are of the same homologous series as the instantly claimed compound. Since the compounds of Fukuyama et al are of the same homologous series as the instantly claimed

compounds, the binding affinity for the Fab fragment is an inherent property of the compound of Fukuyama et al.

Affinity chromatography

Limitations directed to affinity chromatography are treated as intended use of the claimed separation matrix. It is well settled that the intended use of a composition or product (e.g. as a cosmetic composition) will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount as instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d, 1647.

Although affinity chromatography need not be considered here, Examiner would like to point out that one skilled in the art would find it obvious to use a solid-phase linked functionality that exhibits affinity for a specific compounds or biological molecule in a chromatography directed at isolation of the said biological molecule or compound.

Objection to claims

Claims 27, 31-32 are objected to a being dependant on a rejected base claim. Search of prior art has failed to uncover biologically active aryl-urea derivative compounds with dichloro substitution on the R2 phenyl ring.

Conclusion

Claims 16-19, 21-23, 26-34 are pending

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Claims 16 and 21 are withdrawn.

Claims 27, 31 and 32 are objected to.

Claims 17-19, 22-23, 26, 28-30 and 33-34 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yevgeny Valenrod/

Yevgeny Valenrod
Patent Examiner
Technology Center 1600

/Daniel M Sullivan/
Supervisory Patent Examiner, Art Unit 1621